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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,021	12/29/2000	Hans-Georg Frank	P66238US0	6410

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EXAMINER
BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
1642	10

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/750,021	Applicant(s) FRANK ET AL.	
	Examiner David J Blanchard	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-7, drawn to a method of making monoclonal antibodies that bind epitopes on the surface of trophoblasts or tumor cells, classified in class 424, subclass 155.1.

   II. Claims 1-7, drawn to a method of making monoclonal antibodies that bind epitopes involved in cell-virus fusion, classified in class 424, subclass 141.1.

   III. Claims 1-7, drawn to a method of making monoclonal antibodies that bind epitopes from endogenous antibodies, classified in class 424, subclass 152.1.

   IV. Claim 1 in part and claims 8-10, drawn to a method of using monoclonal antibodies for identifying low molecular weight peptides from a library that have a high binding affinity, classified in class 435, subclass 7.1

   V. Claims 11 and 12, drawn to an antibody, classified in class 530, subclass 388.1.

   VI. Claims 13-15, drawn to a low molecular weight peptide, classified in class 530, subclass 300.

VII. Claims 16 and 17 in part, drawn to a method of using the low molecular weight peptide for tumor treatment, classified in class 424, subclass 184.1.

VIII. Claims 16 and 17 in part, drawn to a method of using the low molecular weight peptide for treating infections, classified in class 424, subclass 184.1

IX. Claims 16 and 17 in part, drawn to a method of using the low molecular weight peptide as a vaccine contraception, classified in class 424, subclass 184.1.

X. Claim 18, drawn to a method of making single chain antibody fragments, classified in class 435, subclass 69.6.

XI. Claim 19, drawn to a method of identifying peptides using the single chain antibody of claim 18, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups V and VI represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. The antibody of Group V and the low molecular weight peptide of Group VI are structurally and chemically different from each other. The peptide is made by translation of mRNA, while the antibody is raised by immunization and can be used to purify the antigen, for example. The antibody of Group V and the low molecular weight peptide of Group VI are patentably distinct because each is structurally and functionally distinct and art on

one would not necessarily be art on the other. The examination of both groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups V and VI are patentably distinct.

The methods of Inventions I-IV, VII-XI differ in the method objectives, method steps and parameters and in the reagents used. Invention I recites method of making monoclonal antibodies that bind epitopes on the surface of trophoblasts or tumor cells; Invention II recites method of making monoclonal antibodies that bind epitopes involved in cell-virus fusion; Invention III recites method of making monoclonal antibodies that bind epitopes from endogenous antibodies; Invention IV recites a method of using monoclonal antibodies for identifying low molecular weight peptides from a library that have a high binding affinity; Invention VII recites a method of using the low molecular weight peptide for tumor treatment; Invention VIII recites a method of using the low molecular weight peptide for treating infections; Invention IX recites a method of using the low molecular weight peptide as a vaccine contraception; Invention X recites a method of making single chain antibody fragments; Invention XI recites a method of identifying peptides using the single chain antibody of claim 18. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups I-IV, VII-XI are separate and distinct in having different method objectives, method steps and different endpoints and thus, are patentably distinct.

Inventions V and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group V can be used in a materially different method such as to purify the antigen, in addition to the materially different method of Group IV.

Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the low molecular weight peptide of Group VI can be used in a materially different method such as making a fusion protein in addition to the materially different methods of Group VII, VIII and IX.

Inventions I and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody of invention V can be made by affinity maturation using V gene repertoires from naïve B lymphocytes, which has materially different steps and processes compared to the method of Group I, II, or III.

Inventions X and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody of invention III can be made by antibody grafting, which has materially different steps and processes compared to the method of Group X.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard, whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any

inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,
David J. Blanchard
703-605-1200

LARRY R. HELMS, PH.D
PRIMARY EXAMINER